## DETAILED ACTION

**Claims 1-5 and 7-20 are presented for examination.**

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's submission filed 3/21/2011 has been received and entered into the present application. Claims 1-5 and 7-20 are pending and are herein examined on the merits.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 7-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lutein Lycopene Carotene Complex Vegicaps® (cited on IDS), in view of Stahl et al. "Carotenoid mixtures protect multilamellar liposomes against oxidative damage: synergistic effects of lycopene and lutein" (cited on IDS), further in view of Auweter et al.

(US Pub No. 2002/0044991) (cited on IDS) taken with Kiokias et al. "Dietary supplementation with a natural carotenoid mixture decreases oxidative stress" (cited on IDS) and Hoshino et al. (US Pat. No. 6869773 B2)

Vegicaps® teaches capsule formulation providing beta-carotene in an amount of 8568 IU (5.13977 mg), Lutein in an amount of 5mg and lycopene in an amount of 5mg.

Stahl et al. teach carotenoid mixtures protect against oxidative damage. Synergism for lycopene and lutein was found in two component mixtures containing one of these compounds together with only one other carotenoid. The most efficient mixture consisted of lycopene and lutein and that combinations of carotenoids are more effective than single compounds in preventing oxidative damage, i.e. they are synergistic (page 307, left col., 2nd & 3rd para.). With regard to claim 3; Stahl et al. further teach suppression of lipid peroxidation by various carotenoids and alpha-tocopherol may be influenced by the site and the rate of radical production. Thus a different compartmentation of the lipophilic antioxidants may be important (page 307, right col., 1st para.).

With regard to claims 4, 5, 14, 15, 19, and 20; Auweter et al. teach preparations of at least two active compounds suitable for the food sector and animal feed sector or for pharmaceutical and cosmetic applications having a multicore structure in which at least two cores of a multicore structure have a different chemical composition, a process for their production and the use of these solid preparations to produce food supplements, and as additive to foods, animal feeds, pharmaceutical and cosmetic preparations (see abstract). The invention relates to solid preparations of at least two

active compounds suitable for the food sector and animal feed sector or for pharmaceutical and cosmetic applications having a **multicore structure**, in particular carotenoid containing dry powders, a process for their production and the use of these solid preparations for producing food supplements and as additive to foods, animal feeds, pharmaceutical and cosmetic preparations [0001]. The objective is achieved according to the invention by solid preparations of at least two active compounds suitable for the food sector and animal feed sector or for pharmaceutical and cosmetic applications in the form of a multicore structure in which at least two cores of a multicore structure have a different chemical composition [0011]. Carotenoids, not only carotenes but also xanthophylls, for example **beta-carotene, lycopene, lutein**, astaxanthin, zeaxanthin, and capsanthin [0022]. Preferred embodiments of the inventive solid preparations are carotenoid-containing dry powders in the form of the multicore structure which comprises at least two of the mentioned carotenoids, selected from the group consisting of carotenes and xanthophylls [0023]. Particular preference is given to those dry powders in which at least two cores (primary particles) comprise one carotenoid or more than one different carotenoid. In particular in the preparations at least two cores comprise only one representative of the carotenoid class of substances [0024]. Very particular preference is given to dry powders comprising a mixture of beta-carotene, lycopene and lutein [0028]. A dry powder of this type comprises a multicore structure of secondary particles in which at least three primary particles have a different carotenoid composition, in each case one particle species comprising only beta-carotene, the second lycopene and the third only lutein

[0029]. The content of .beta.-carotene, lycopene and lutein in the inventive dry powders is generally from 0.1 to 50% by weight, preferably from 1 to 35% by weight, particularly preferably from 5 to 25% by weight, very particularly preferably from 8 to 20% by weight, based on the total amount of the formulation [0030]. The quantitative ratio of the carotenoids present in the dry powder is 1 part of beta-carotene, from 0.02 to 20 parts of lycopene and from 0.02 to 20 parts of lutein, preferably 1 part of beta-carotene, from 0.1 to 5 parts of lycopene and from 0.1 to 5 parts of lutein, particularly preferably 1 part of beta-carotene, from 0.2 to 2 parts of lycopene and from 0.1 to 2 parts of lutein, very particularly preferably 1 part of beta-carotene, from 0.3 to 1.2 parts of lycopene and from 0.1 to 0.8 parts of lutein. [0031]. Food supplement preparations and pharmaceutical preparations which comprise the inventive dry powders are, inter alia, tablets, sugar-coated tablets and hard and soft gelatin capsules. Preferred food supplement preparations are tablets into which the dry powders are co-incorporated, and soft gelatin capsules in which the carotenoid-containing multicore structures are present as oily suspension in the capsules. The carotenoid content in these capsules is from 0.5 to 20 mg of .beta.-carotene, from 0.5 to 20 mg of lycopene and 0.5 to 20 mg of lutein, preferably from 1 to 15 mg of beta-carotene, from 1 to 15 mg of lycopene and from 1 to 10 mg of lutein, particularly preferably from 2 to 10 mg of beta-carotene, from 2 to 10 mg of lycopene and from 1 to 5 mg of lutein [0055].

With regard to claim 13; Kiokias et al. teach dietary supplementation with a natural carotenoid mixture decreases oxidative stress. Participants supplemented with the fish oil containing the carotenoid mixture showed a clear increase in the plasma

levels of beta and alpha carotenes, lycopene and lutein (page 1137, right col., last para.)

Hoshino et al. teach aging is caused by oxidative damage (see col. 6, lines 52-53).

It is well settled that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In other words, where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. See In reBest, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Therefore, it is obvious that the same composition with the same concnetration used for the same effect as the claimed invention will possess the same properties and the decreasing age associated DNA damage in the subject are the physical properties of carotenoid mixture. These properties and characteristics of carotenoid mixture, beta-carotene, lycopene, and leutin are inseparable of the instant claimed invention. Therefore, one of ordinary skill in the art would combine the teachings of above references since all references are directed toward a composition and method comprising mixture of carotenoid dietary supplementation and its role on oxidative damage.

It would have been obvious to a person skilled in the art to employ the teachings

of the above mentioned references considering that such references teach all the components of the claimed invention in a method for decreasing oxidative damage and pharmaceutical formulation comprising an effective daily dose of lutein, lycopene, and beta-carotene.

One skilled in the art would have been motivated to employ the teachings of the mentioned above references since they relate to a method and composition comprising of carotenoid species in a nutritional and pharmaceutical formulation. The above references make clear that the claimed components have been previously used in a nutrient supplement composition and method of decreasing oxidative damage in a subject. As combined, the references would have resulted in the claimed invention.

Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, prima facie obvious over the cited arts.

### *Response to Arguments*

Applicant's arguments and remarks are moot in view of new ground of rejection.

### *Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Lundgren, can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner June 13, 2011
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